

and the percentage of time each person will devote to the program.

6. Budget and Justification (not scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with the stated objectives and planned program activities.

7. Human Subjects (not scored)

The extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. semiannual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the "Where To Obtain Additional Information" section of this announcement.

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement.

AR-1 Human Subjects Requirements
AR-2 Requirements for Inclusion of

Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-21 Small, Minority, Women-Owned Businesses

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 317(k)(2), 391, 392, 394, and 394A [42 U.S.C. 241(a), 247b(k)(2), 280b, 280b-1, 280b-2, 280b-3] of the

Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page on the Internet: <http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements." To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

To obtain business management technical assistance, contact: Angelia Hill, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01034, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341-4146, Telephone (404) 488-2785, Email address aph8@cdc.gov.

For program technical assistance, contact: Judy Stevens, Ph.D., Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway N.E., Mailstop K63, Atlanta, GA 30341-3724, Telephone (770) 488-4649, Email: jas2@cdc.gov.

Dated: April 11, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01062]

Programs to Prevent the Emergence and Spread of Antimicrobial Resistance in Swine As Food Animals; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) is implementing a multifaceted effort to address the problem of antimicrobial resistance. As part of this, CDC, in collaboration with the Food and Drug Administration Center for Veterinary Medicine, announces the availability of fiscal year (FY) 2001 funds for a cooperative

agreement program to provide assistance for the development and evaluation of demonstration projects to prevent and control the emergence and spread of antimicrobial resistance in swine as food animals. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases. For more information visit the internet site: <http://www.health.gov/healthypeople>.

The purpose of this program is to develop, implement, and evaluate a prudent antimicrobial use project to reduce the emergence, prevalence, and spread of antimicrobial resistance among target pathogens in swine as food animals.

The intention of this project is to develop and evaluate a "prudent use of antimicrobial agents" program in swine as food animal. It is hoped that this project would serve as a model towards the long-term goal of development of a national campaign for prudent antimicrobial use in swine as a food animal, and that additional resources towards achieving this goal would be provided by veterinary and animal industry organizations.

Programs should address the problem of antimicrobial resistance through interventions potentially including, but not limited to:

1. Promoting more judicious antimicrobial use (e.g., using antimicrobial agents only when needed, using appropriate doses of antimicrobial agents),

2. Reducing transmission of antimicrobial resistant microorganisms among food animals through good management practices,

3. Preventing colonization and infection of animals by pathogens through the use of probiotics, and

4. Improving the ability to provide effective narrow spectrum therapy by rapidly and accurately diagnosing resistant microorganisms through the use of improved laboratory testing procedures and improved quality and flow of laboratory data.

It is envisioned that the funded project will use a combination of approaches to achieve judicious antimicrobial use and other changes that will result in decreased appearance and spread of resistance. The funded project will also be expected to conduct a multifaceted evaluation of many aspects of the program, including assessing the costs and any cost-savings associated with any proposed intervention.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and

their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement contract, loan, or any other form.

C. Availability of Funds

Approximately \$75,000 is available in FY 2001 to fund one award. It is expected that the award will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of up to 3 years. The funding estimate may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities) and CDC will be responsible for conducting activities under 2. (CDC Activities).

1. Recipient Activities

a. Utilizing the selected food animal focus (swine) and the defined foodborne pathogens of interest (e.g., Salmonella, Campylobacter), develop a study protocol and describe the partnerships necessary to conduct the study, including a veterinary diagnostic laboratory, veterinary professional associations, and animal commodity groups.

b. Selecting the study population and identifying a population of adequate size for the purpose of the study. The population will likely include several farms and producers.

c. Defining, collecting, and analyzing baseline data, so that evaluation of the interventions can be done. This includes at a minimum collecting prevalence data on antimicrobial resistance among the target pathogens and measuring antimicrobial agent usage pattern before the intervention.

d. Designing and implementing an intervention promoting judicious antimicrobial use and other approaches to reducing antimicrobial resistance: It is anticipated that this will involve developing coalitions among veterinary professional societies, producers,

commodity groups, and others, as well as implementing specific strategies. These strategies may include peer-education of veterinarians, producers, formulary guidelines, prescribing restrictions, and strategies which are likely to reduce transmission of pathogens. The choice of strategies should be justified based on the nature of the study population, and the infrastructure in which the study population receives veterinary care.

e. Measuring the effects of the intervention:

(1) Measuring the change in rates of antimicrobial resistance of organisms over time. Organisms whose resistance can be measured could include: human foodborne pathogens, animal pathogens, organisms that are opportunistic human pathogens (e.g., Enterococcus), normal animal fecal flora.

(2) Measurement of antimicrobial resistance should be accomplished by a laboratory with proven ability to perform measurements using a standard approved methodology, yielding a quantitative measure of resistance, such as mean inhibitory concentration or zone size.

(3) As decreases in resistance, as a result of the program, may take several months to years to manifest themselves, the recipient is responsible for measuring outcomes related to how well the interventions have been implemented.

(4) Measuring cost implications of the intervention. This should include impact of the intervention on direct costs (e.g., costs of antibiotics, veterinary care visits, duration of illness, etc.) and indirect costs (e.g., lost productivity, decreased feed efficiency, etc.). Costs of the intervention program must be differentiated from those of the evaluation.

(5) Consideration should be given to parallel measurements in a non-intervention group of animals, to better define the impact of the intervention.

f. Dissemination of research findings: Disseminating research results by appropriate methods such as publication in journals, presentation at meetings, conferences, etc.

2. CDC Activities

CDC, in collaboration with Food and Drug Administration Center for Veterinary Medicine, will provide technical assistance in the design and conduct of the research as resources permit. This may include:

a. Providing technical assistance in the design and conduct of the project, including intervention methods and analytic approach;

b. Performing selected laboratory tests as appropriate;

c. Assisting in data management, the analysis of research data, and the interpretation and dissemination of research findings, as appropriate; and

d. Assisting in the design of the evaluation, in particular, in the identification of outcome measures that will allow for later analysis of economic benefits.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 double-spaced pages (excluding appendices), printed on one side, with one inch margins, and unrounded (12 point) font, unrounded and unstapled.

F. Submission and Deadlines

Letter of Intent

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application are requested to inform CDC of their intention. Notification should include the following information: (1) Announcement number 01062; (2) name and address of institution; and (3) name, address, and phone number of contact person.

On or before May 15, 2001, the Letter of Intent should be provided by facsimile, postal mail, or E-mail, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and five copies of PHS 398 [(OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398)]. Forms are in the application kit.

On or before June 15, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information Section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated

U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 Points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this program.

2. Capacity and Personnel (30 Points Total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. This includes the capacity to conduct quality laboratory measurements. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research and programs related to that proposed as evidenced by curriculum vitae, publications, etc. (15 points)

c. Extent to which applicant includes letters of support from non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate as described in the operational plan. (5 points)

3. Objectives and Technical Approach (60 Points Total)

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this program and which are measurable and time-phased. (10 points)

b. Extent to which the applicant describes swine as the population for study, including whether the results of a study in this population will be generalizable to other populations in the United States. Extent to which the applicant identifies microbes/resistance patterns for study that are of public

health importance. (10 points) Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Recipient Activities. Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for developing and conducting the proposed program and evaluation and extent to which the plan is adequate to accomplish the study objectives. The extent to which applicant describes the existence of or plans to establish partnerships. (20 points)

c. Extent to which the applicant describes any adequate and appropriate collaboration during various phases of the project. (10 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results (including laboratory data, data on prescribing practices, and data on direct costs and charges and indirect costs), as well as plans for evaluating progress toward achieving project objectives. (10 points)

4. Budget (Not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

5. Animal Subjects (Not Scored)

Does the application adequately address the requirements of PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. progress reports (semiannual);
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I.

- AR-3 Animal Subjects Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

AR-15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. Sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address <http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements".

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2753, Email address: gcg4@cdc.gov.

For program technical assistance, contact: Frederick Angulo, DVM, PhD, Medical Epidemiologist, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta, GA 30333, Telephone: (404) 639-3623, Email address: fja0@cdc.gov.

Dated: April 11, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegations of Authority

Notice is hereby given that I delegate to the Director, Office of Refugee Resettlement, with authority to redelegate, the following authority vested in the Assistant Secretary for Children and Families by the Secretary